Sectt. H-37—[illegible]—37-10-47.

E. P. H (1947) Department.

4 SERIES.

G.O. No 3714. P. H

2

Dated 10-11-47

[Despatch Abstract.]

Drugs - Drugs Rules, 1945 - Testing of Patent and Proprietary medicines - Papers - Forwarded.

No.F.1.-3/47-D.
Government of India.
Department of Health.
New Delhi, the 18th July 1947.

From

Herbans Singh, Esquire,
Asst. Secretary to the Government of India

To

The Secretary to the Government of Madras,
Education and Public Health Department, Madras.

Sub: Testing of patent and proprietary medicines.

Sir, I am directed to refer to paragraph 6 of this Department letter No.1-3/47-D, dated the 2nd May 1947 and to say that the position is as follows:-

Under Section 18(a) (i) of the Drugs Act, 1940, no drug can be manufactured, stocked or sold which is not of standard quality. In the case of patent or proprietary medicines with undisclosed formulae which are registered at the Central Drugs Laboratory the standard to be complied with is the formula disclosed to the Central Drugs Laboratory - VIDE - the Schedule to the Act. An Inspector taking the sample of such a drug under section 23 of the Act has to send the sample to a Government analyst for test or analysis. Under section 25 of the Act the Government Analyst to whom a sample is sent has to analyse the sample and send a report to the Inspector. The report or certificate of the Government Analyst will be in Forme No.13 of the Drugs Rules. In it the Government Analyst will have to express his opinion whether the sample is of standard quality or not. In the case of the class of drugs under consideration he will not be able to express an opinion as the secret formula will be in the custody of the Director of the Central Drugs Laboratory - VIDE rules 10 and 11 of the Drugs Rules 1945. To meet this difficulty the best course seems to be to allow Provincial Governments to appoint the Director of the Central Drugs Laboratory as Government Analyst for the Provinces under section 20 of the Drugs Act in respect of patent and proprietary drugs with undisclosed formulae registered at the Central Drugs Laboratory. If this is done, in the case of such drugs the Inspector can send the sample under section 23(4) of the Act to the Director of the Central Drugs Laboratory for report in form 13. If the Director acting as Government Analyst is of the opinion that the sample is of standard quality, he will merely state such opinion without disclosing the protocols of the tests applied. (This would be necessary to preserve the secrecy of the formula.) In case, however, the Director is of opinion that the sample referred to him is not of standard quality, and if the case is one which deserves to be prosecuted, the Director can, under the proviso to rule 13 of the Drugs Rules, get the sanction of the Central Government, and include in the certificate the full reasons for his opinion why the sample is not of standard quality. The Inspector on getting the report can take further action to prosecute the case. For this purpose certain amendment to the Drugs Rules will be necessary as shown in the attached draft notification which the Government of India propose to publish after consulting the Drugs Technical Advisory Board.

I am to enquire whether the Provincial Government agree to appoint the Director, Central Drugs Laboratory, as their Government Analyst in respect of patent and proprietary medicines with undisclosed formulae registered at the Central Drugs Laboratory and whether they agree to the proposed amendments to the Drugs Rules. If they agree, the Central Government will consult the Drugs Technical Advisory Board on behalf of itself and the Provincial Governments and communicate to the Provincial Governments the views of the Board. Further action for the amendment of the Central and Provincial Rules and for the appointment of the Director, Central Drugs Laboratory as Government Analyst for this class of drugs can be taken after the views of the Board have been obtained. The favour of an early reply is requested.

I have the honour to be, Sir, Your most obedient servant,
Sd. Harbans Singh, Asst.Secy.

pto.

GOVERNMENT OF MADRAS
Education & Public Health Deptt

Letter/ Ref.No. 59278 G1/47-2, P.H., dt. 2-9-1947.

To

The Secretary to the Government of India,
Department of Health (India), New Delhi.

Sir,

Testing of patent and proprietary medicines.

With reference to the Government of India's letter No. F.1-3/47-D dated 1st July 1947, I am directed to state that this Government agree to appoint the Director of the Central Drugs Laboratory as their Government Analyst in respect of patent and proprietary medicines with undisclosed formulae registered at the Central Drugs Laboratory. I am also to state that this Government agree to the Drugs Technical Advisory Board being consulted for the purpose of making an amendment to the Provincial Drugs Rules as indicated in the Government of India's letter cited above. This Government await the views of the Drugs Technical Advisory Board in the matter.

Your obedient servant,
Sd. x x
Secy.to Government.

Copy to Surgeon-General.

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E. & P.H.(G.1) Deptt.

Extract from the file relating to C.No.63828. (Drugs) Rules, 1945 - Question of bringing preparations containing substances mentioned in Schedule H within the ambit of rule 65(9).)

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Please see the Government of India's letter No.F1.31./47-D dated 28th October 1947. It may take a long time for the Provincial Governments to send their replies to the Government of India and for the Drugs Technical Advisory Board to give their views in the matter thereafter. The Government of India state that the views of the Board will be furnished to this Government IN DUE COURSE. For orders whether the case should be kept open with reference to the orders of J.S. on p. 8 ante or whether the case may be closed and a call entry noted six month's hence.

S.S.D./3-11-47.

A call may be noted on each such case for 6 months and the papers closed.

S.O.C./4-11-47.

With reference to the orders of J.S. above, this case may be recorded and a call noted six months hence.

G.O.Ms.No.3714,P.H.dt.10-11-47.
Sd. x x /8-11-47.

Abstract:
Drugs - Drugs Rules,1945 - Testing of Patent and proprietary medicines - Papers recorded.

/True copy/

Office Assistant,
Madras Record Office.

PSR. 3-12-53.